TEXAS DEPARTMENT OF HEALTH

KIDNEY HEALTH CARE RULES

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Associateship for Family Health
Bureau of Kidney Health Care

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CONTENTS

§61.1. General.

(a) Purpose. The purpose of this Chapter is to establish rules for Kidney Health Care (KHC). The authority for these rules is granted in the Texas Health and Safety Code, Chapter 42.

(b) Delegation of Authority. Under the Texas Health and Safety Code, Chapter 11, §11.013, the Board of Health (board) delegates to the Commissioner of Health (commissioner), or to the person acting as commissioner in the commissioner's absence, the authority to administer KHC, exclusive of rulemaking authority.

(c) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) Access surgery - The surgical procedure which creates or maintains the access site necessary to perform dialysis.

(2) Action - A denial, termination, suspension or reduction of KHC-covered services or eligibility.

(3) Allowable amount - The maximum amount that KHC will pay or reimburse for a covered benefit or service.

(4) Applicant - An individual whose application for KHC benefits has been submitted through a participating facility and has not received a final determination of eligibility. This includes an individual whose application is submitted by a representative or person with legal authority to act for the individual.

(5) Board - The Texas Board of Health.

(6) Claim - A request for payment or reimbursement of services.

(7) Commissioner - The commissioner of the Texas Department of Health.

(8) Co-pay liability - The portion of the allowable amount for which a KHC recipient is responsible.

(9) Covered services - Drugs, transportation, pharmaceutical products, medical care, treatment, services or equipment which have been approved by KHC for payment.

(10) Department - The Texas Department of Health.

(11) End-Stage Renal Disease (ESRD) - The final stage of renal impairment which is irreversible and permanent and requires dialysis and/or kidney transplant to reduce uremic symptoms and/or prevent the death of the patient.

(12) EOB - A form, in paper or electronic format, which provides an explanation of benefits. It is used to explain a payment or denial of a claim.

(13) Fair hearing - The informal hearing process the department follows under §61.11 of this title (relating to Notice and Fair Hearing).

(14) Final decision - A decision that is reached by a decision maker after conducting a fair hearing under this title.

(15) HCFA - Stands for the Health Care Financing Administration.

(16) Interim approval - The approval given by KHC to a facility which has applied for participation as a KHC facility but has not executed a contract with KHC.

(17) KHC - Stands for the Kidney Health Care program.

(18) Medical benefits - Any medical treatment or procedure approved by KHC as a covered service.

(19) Participating facility - Any KHC approved or interim approved facility including:

(A) outpatient dialysis facilities with whom KHC has contracted;

(B) out-of-state outpatient dialysis facilities with whom KHC has contracted;

(C) home health agencies with whom KHC has contracted;

(D) hospitals located and licensed in Texas that are:

(i) approved by Medicare; and

(ii) an approved Texas Medicaid provider;

(E) out-of-state hospitals that are:

(i) approved by Medicare; and

(ii) an approved Texas Medicaid provider;

(F) military or Veterans Administration hospitals located in Texas which have a renal unit approved by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA).

(20) Participating pharmacy - Any KHC and Texas Medicaid Vendor Drug Program approved pharmacy licensed to operate within the United States and its territories, including mail order pharmacies.

(21) Provider - Any individual or entity with KHC approval to furnish covered services to KHC recipients.

(22) Recipient - An individual who is eligible to receive KHC benefits.

(23) Reconsideration - The administrative review process KHC follows under this chapter.

(24) Suspended benefits - Eligibility for benefits or claims which are denied and/or held pending satisfaction of a KHC request or requirement.

(25) TDCI – Stands for the Texas Drug Code Index. This microfiche list of drugs by National Drug Code includes drugs and drug products approved by the department for payment as a benefit of KHC. Not all drugs listed on the TDCI are covered by KHC; however, all drugs covered by KHC are included on the TDCI.

(26) VDP – Stands for the Texas Medicaid Vendor Drug Program.

§61.2. Recipient Requirements.

(a) A person shall meet all of the following requirements to be eligible for Kidney Health Care (KHC) benefits:

(1) have a diagnosis of end-stage renal disease (ESRD) certified by a licensed physician who is board eligible or board certified in internal medicine, nephrology, or pediatric nephrology;

(2) meet the Medicare criteria for ESRD;

(3) be receiving a regular course of chronic renal dialysis treatments or have received a kidney transplant;

(4) be a resident of Texas as determined in §61.3 of this title (relating to Residency and Residency Documentation Requirements); and not be:

(A) incarcerated in a city, county, state, or federal jail, or prison;

(B) a ward of the state;

(C) a Medicaid-eligible nursing home recipient; or

(D) a Medicaid recipient under the age of 21;

(5) submit an application for benefits through a participating facility; and

(6) have, or the person(s) who has a legal obligation to support the applicant have, an adjusted gross income (AGI) of less than $60,000. Income reported as "joint income" is considered as one income and may not be divided in computing the recipient's co-pay liability. The person or persons who have a legal obligation to support the recipient will be determined by the applicable state law.

(b) A recipient may have all KHC benefits modified, suspended or terminated for any of the following reasons:

(1) failure to maintain Texas residency or, upon demand, furnish evidence of such using the criteria in §61.3 of this title (relating to Residency and Residency Documentation Requirements);

(2) failure to provide income data as requested by the department to determine continued KHC eligibility and co-pay liability;

(3) failure to reimburse the department as requested for overpayments made to the recipient;

(4) failure to apply for medical, drug, and transportation benefits under Title XIX, Social Security Act (Medicaid), if the applicant meets income and other eligibility requirements for Medicaid;

(5) failure to inform KHC within 30 days of changes in the following:

(A) permanent home address;

(B) treatment status;

(C) insurance coverage;

(D) location of treatment;

(E) the round trip mileage from the recipient's permanent home address to the location of treatment; or

(F) changes in income or financial qualifications which would affect either the recipient's eligibility or co-pay liability;

(6) recipient is incarcerated in a city, county, state, or federal jail, or prison;

(7) recipient regains kidney function or voluntarily stops treatment for ESRD;

(8) recipient becomes a ward of the state;

(9) KHC determines that the recipient has made a material misstatement or misrepresentation on their application or any document required to support their application;

(10) KHC determines that the recipient has submitted false claim(s); or

(11) KHC has not paid a claim for benefits on behalf of the recipient during any period of 12 consecutive months.

(c) Any action taken under subsection (b) of this section does not release the recipient, or the person(s) with legal obligation to support the recipient, of any financial obligation owed to KHC.

(d) A recipient may have a portion of their KHC benefits modified, suspended or terminated, or claim(s) denied for any of the following reasons:

(1) failure to receive services through participating facilities, pharmacies, and providers;

(2) failure to submit claims for reimbursement within filing deadlines, as specified in §61.8 of this title (relating to Claim Filing Deadlines);

(3) failure to apply for benefits under Title XVIII, Social Security Act (Medicare);

(4) failure to continue premium payments on health insurance plans under Medicare, individual or group health insurance plans and prepaid medical plans, where eligibility was effective prior to KHC eligibility; or

(5) failure to provide authorization for Medicare premium payments by KHC as specified in §61.6 of this title (relating to Limitations and Benefits Provided); if not eligible for Medicare premium-free hospitalization.

(e) In order to requalify for KHC, an applicant shall reapply and requalify for KHC benefits when eligibility for KHC benefits is terminated.

(f) A recipient who loses eligibility will not be reinstated until all outstanding debts owed to KHC by the recipient are paid or arrangements acceptable to KHC are made for payment.

(g) A recipient whose benefits are modified, suspended or terminated, or whose claim(s) are denied, may appeal KHC's decision under the procedure contained in §61.10 of this title (relating to Notice of Intent to Take Action and Reconsideration) and §61.11 of this title (relating to Notice and Fair Hearing).

(1) KHC may not terminate KHC participation until a final decision is rendered under the department's reconsideration and fair hearings process, if a reconsideration or hearing is requested by the recipient.

(2) KHC may withhold payments on claims pending final decision under the department's reconsideration and fair hearings process.

(3) KHC shall release withheld payments and reinstate participation in KHC if the final determination is in the recipient's favor.

§61.3. Residency and Residency Documentation Requirements.

(a) The following conditions shall be met by an applicant and maintained by a recipient to satisfy the residency requirements in this section:

(1) physically reside within the State; and

(2) maintain a home or dwelling within the State.

(b) If the applicant is a minor child; a legal dependent of, and residing with, a resident (such as an adult child or spouse); or a person under a legal guardianship, then the parent or parent(s), resident providing support, or legal guardian of the applicant shall meet all of the requirements of subsection (a) of this section.

(c) If the applicant is a parent residing with their adult child who is a resident of Texas, residency may be determined through the adult child. If the applicant is a parent being supported by their adult child, whether or not the child is a resident of Texas, the residency may be determined by the adult child providing the required documents supporting the Texas residency of the parent. These provisions apply even if no legal guardianship has been established.

(d) All documents submitted to establish the residency of an applicant shall be in English or, if required by KHC, accompanied by an accurate English translation.

(1) An applicant who is currently a Texas resident and has been currently approved to receive Texas Medicaid benefits is not required to provide additional residency verification.

(2) An applicant, or person establishing residency for the applicant under subsections (b) and (c) of this section, may submit copies of any two of the following documents as evidence of residency. All documents shall be in the applicant's name, or in the name of the person establishing residency for the applicant, and provide some verification of a Texas address or domicile. Each of the following documents listed may only be counted once:

(A) a valid Texas driver's license, or an identification card issued by the Texas Department of Public Safety;

(B) a valid Texas voter's registration card, or a copy of a validated (at the county clerk's office) application for a voter's registration card;

(C) a current Texas motor vehicle registration or automobile license plate registration renewal form;

(D) a mortgage payment receipt from any of the three months immediately preceding the date of the application;

(E) a rent payment receipt from any of the three months immediately preceding the date of the application;

(F) a notarized statement reflecting that the applicant is currently receiving rent-free housing. The statement must be signed by the individual providing the rent-free housing and must include the address and phone number of the individual providing the rent-free housing;

(G) a utility payment receipt from any of the three months immediately preceding the date of the application;

(H) a Texas property tax receipt for the most recently completed tax year;

(I) a payroll or retirement check dated within the three months immediately preceding the date of the application;

(J) employment/unemployment records prepared within the three months immediately preceding the date of the application;

(K) a statement from a financial institution issued within the three months immediately preceding the date of the application; or

(L) social security supplemental income or disability income records or social security retirement benefit records issued within the three months immediately preceding the date of application.

(e) Applications submitted under subsections (b) and (c) of this section shall also include evidence of the legal relationship between the applicant and the resident, such as:

(1) a marriage license or declaration of non-ceremonial marriage to document the marriage of the applicant and spouse;

(2) a birth certificate establishing the parent/child relationship between the applicant and the resident;

(3) a final order showing the appointment of the resident as guardian for the minor or adult ward;

(4) a final order naming the applicant's managing conservator; or

(5) an income tax return showing name and relationship of the applicant to the resident.

(f) Any difference between the name of the applicant and the name on any document must be explained by additional documentation (Example: marriage license, divorce decree, or adoption decree).

§61.4. Applications. Persons meeting the eligibility requirements set forth in §61.2(a)(1), (2), (3), (4), and (6) of this title (relating to Recipient Requirements) must make an application for benefits through a Kidney Health Care (KHC) participating facility.

(1) Complete application. A complete application is required before any eligibility determination will be made. A complete application shall consist of all of the following:

(A) a complete and notarized Application for Benefits, with the applicant's, or the applicant's representative's, original signature or "mark";

(B) a copy of the completed, signed and dated (MM/DD/YY) Health Care Financing Administration (HCFA) End-Stage Renal Disease Medical Evidence Report;

(C) documentation of Texas residency as required by §61.3 of this title (relating to Residency and Residency Documentation Requirements);

(D) a copy (front and back) of the applicant's social security card issued by the Social Security Administration, or an allowable substitute, as follows:

(i) a copy of a Social Security Administration document which verifies the social security number; or

(ii) a copy of a valid Medicare or Medicaid card, if the Medicare account was established in the applicant's own social security number and the social security number is printed on the Medicare or Medicaid card.

(E) applicant financial data. Acceptable data to establish the applicant's financial qualifications shall be submitted with the application. An adult applicant who is currently a Texas Medicaid recipient is not required to provide financial data. Changes in income or financial qualifications which would affect the applicant's eligibility shall be reported to KHC. The applicant may attach any of the following documents to verify income:

(i) A copy of the first page of either the applicant's, or the person(s) legally obligated to support the applicant's, IRS individual income tax return form for the most recently completed tax year or an estimated or declared income for the current tax year on the Application for Benefits.

(ii) Applicants who do not file a federal income tax return may submit documentation of financial assistance, income, or retirement benefits.

(2) Incomplete application. Any application which does not meet all of the requirements of paragraph (1) of this subsection is incomplete. Incomplete applications may be returned to the submitting person or entity for correction or completion.

(3) Eligibility date for KHC benefits. The KHC eligibility date will be the later of:

(A) 30 days prior to the date KHC receives a complete application;

(B) the date the applicant is no longer considered a ward of the state;

(C) the date the applicant is no longer incarcerated in a city, county, state, or federal jail, or prison;

(D) the date the applicant received the first chronic dialysis treatment or hospitalization for transplant surgery as reflected on the HCFA 2728; or

(E) the date the applicant established Texas residency.

(4) Eligibility date for reinstatement of KHC benefits. If KHC benefits are terminated, the eligibility date for any subsequent benefit period will be the date on which KHC receives a subsequent completed application for KHC benefits.

§61.5. Recipient Co-Pay Liability. Kidney Health Care (KHC) may establish co-pay liability standards for all KHC recipients.

§61.6. Limitations and Benefits Provided.

(a) Benefits payable by Kidney Health Care (KHC) are as follows:

(1) KHC allowable out-patient drugs and drug products included on the Texas Drug Code Index (TDCI) (a list of KHC allowable drugs is available upon request from KHC, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756);

(2) covered transportation;

(3) access surgery (hospitalization, surgeon's fees, assistant surgeon's fees, anesthesiologist' fees, Certified Registered Nurse Anesthetist fees);

(4) out-patient chronic maintenance dialysis treatments;

(5) in-patient chronic maintenance dialysis treatments (excluding treatment for emergency/acute dialysis); and

(6) Medicare Part A and B premiums, if qualified. To qualify for this benefit, recipients:

(A) cannot be eligible for:

(i) "premium free" Part A coverage; or

(ii) Medicaid to pay their Medicare premiums;

(B) shall apply and be accepted for Medicare hospital and medical insurance;

(C) shall sign a Medicare agreement which allows KHC to make Medicare premium payments in their behalf; and

(D) shall promptly submit all Medicare premium due notice statements to KHC for payment.

(b) All KHC benefits are limited to services received in Texas except for:

(1) covered services received from a participating out-of-state facility; and

(2) KHC allowable drugs submitted by any participating out-of-state pharmacy.

(c) Depending on the recipient's eligibility status, KHC will pay for covered services up to a maximum allowable amount per recipient based upon:

(1) available funds;

(2) established limits for covered services by type or category;

(3) any contract between the department and the recipient's participating facility;

(4) a contract between the department and the recipient's participating provider;

(5) the reimbursement rates established by the department;

(6) any co-pay liability rates as established by the department; and

(7) any third-party liability.

(d) Recipients who are eligible for transportation benefits under the Medicaid Transportation Program (MTP), including those on suspended status under MTP, are not eligible to receive KHC transportation benefits.

(e) Recipients eligible for drug coverage under a private/group health insurance plan are not eligible to receive KHC drug benefits. A recipient that has exhausted drug coverage under a private/group health insurance plan may be eligible to receive drug benefits from KHC.

(f) Access surgery benefits are payable only if the services were performed on or after the date Texas residency was established and not more than 180 days prior to the recipient's KHC eligibility effective date.

(g) KHC medical benefits are payable during the Medicare three-month qualifying period to recipients who do not have Medicare coverage. Benefits are payable for services received on or after the KHC eligibility effective date. The three-month qualifying period shall be calculated from the first day of the month the recipient begins chronic maintenance dialysis. If a recipient becomes eligible for Medicare during the three-month period, KHC medical benefits shall not be payable from the date of Medicare eligibility.

(h) Limited medical benefits are available beyond the qualifying period for non-Medicaid eligible recipients who have applied for and have been denied Medicare coverage based on ESRD. Recipients shall submit a copy of an official Social Security Administration Medicare denial notification (based on chronic renal disease) to the department. Transplant patients who have been successfully transplanted for three years or more are not eligible for limited medical benefits.

(i) Recipients eligible for hospital and medical benefits from Medicare, Medicaid, the Veterans Administration, the military, or other government programs are not eligible to receive KHC medical benefits.

(j) Recipients eligible for hospital and medical benefits from private/group health insurance may be eligible for KHC medical benefits. If the recipient's third party coverage has a liability equal to or greater than the KHC allowable rates, KHC will not be liable for payment.

(k) KHC is payor of last resort. All third parties must be billed prior to KHC. The Commissioner of Health (Commissioner) may waive this requirement in individually considered cases where its enforcement will deny services to a class of end-stage renal disease (ESRD) patients because of conflicting state or federal laws or regulations, under the Texas Health and Safety Code, Chapter 42, §42.009.

(l) The department may restrict or categorize covered services to meet budgetary limitations. Categories will be prioritized based upon medical necessity, other third party

eligibility and projected third party payments for the different treatment modalities, caseloads, and demands for services. Caseloads and demands for services may be based on current and/or projected data. In the event covered services must be reduced, they will be reduced in a manner that takes into consideration medical necessity and other third party coverage. The department may change covered services by adding or deleting specific services, entire categories or by making changes proportionally across a category or categories, or by a combination of these methods.

§61.7. Claims Submission and Payment Rates.

(a) Drug claims shall be submitted electronically to the Vendor Drug Program (VDP) by the participating pharmacy through the VDP electronic claims management system, except when VDP allows or requires paper submissions.

(b) Claims for medical benefits shall be submitted to Kidney Health Care (KHC) by the provider who rendered the service(s) to the KHC recipient.

(c) Recipients who are not eligible for transportation benefits under the Medicaid Medical Transportation Program (MTP) shall submit claims to KHC for transportation reimbursement.

(d) Payments will be made using rates in effect on the date services were rendered, and not prospectively.

(e) Claims for medical benefits which are submitted for third party payment and the third party payor has denied the claim without written explanation shall be submitted to KHC with the following information:

(1) written explanation by the provider or recipient of the reason for the denial;

(2) coverage termination dates, if applicable; and

(3) the name and phone number of the third party payor's representative providing the information.

§61.8. Claim Filing Deadlines.

(a) Claims shall be received by Kidney Health Care (KHC) within the claim filing deadlines established in this section. Claims which are incomplete or incorrect will not be paid until they are completed or corrected. Claims which are not received by KHC within the deadlines established in this section shall not be considered for payment.

(b) Hospital claims for in-patient services, other than access surgery, shall be received by KHC the later of:

(1) 95 days from the last day of the month in which services were provided;

(2) 60 days from the date on the third party explanation of benefits (EOB), but not later than 180 days from the date of discharge; or

(3) 60 days from the date on the KHC notice of eligibility.

(c) Claims for out-patient dialysis services from contracted facilities shall be received by KHC the later of :

(1) 95 days from the last day of the month in which services were provided;

(2) 60 days from the date on the third party EOB, but not later than 180 days from the date of service;

(3) 60 days from the date on the KHC notice of eligibility; or

(4) 60 days from the date on the contract approval letter for newly contracted facilities, but not later than 180 days from the date of service.

(d) Claims for physician services, other than access surgery, shall be received by KHC the later of:

(1) 95 days from the last day of the month in which services were provided;

(2) 60 days from the date on the third party EOB, but not later than 180 days from the date of service; or

(3) 60 days from the date on the KHC notice of eligibility.

(e) Claims for travel reimbursement shall be received by KHC the later of:

(1) 95 days from the last day of the month in which services were provided; or

(2) 60 days from the date on the KHC notice of eligibility.

(f) Claims for access surgery charges shall be received by KHC the later of:

(1) 95 days from the last day of the month in which services were provided;

(2) 60 days from the date on the third party EOB, but not later than 180 days from the recipient's KHC eligibility effective date; or

(3) 60 days from the date on the KHC notice of eligibility.

(g) Claims for drug charges shall be submitted to the Vendor Drug Program (VDP) in accordance with VDP drug claim filing deadlines.

(h) Resubmitted claims, other than drug claims, shall be received by KHC within the deadlines established under subsections (b), (c), (d), (e), and (f) of this section, or within 180 days from the date of the KHC return letter or KHC EOB, whichever is later. Resubmitted claims shall:

(1) be resubmitted with a copy of the KHC return letter or KHC EOB, if applicable;

(2) be resubmitted on the original claim form, if applicable; and

(3) contain no new or additional charges for service.

§61.9. Participating Facilities, Participating Pharmacies, and Providers.

(a) The following criteria must be met for a facility, pharmacy, or provider to qualify for participation in Kidney Health Care (KHC).

(1) Outpatient dialysis facilities and licensed Class B home health agencies shall execute a contract with KHC, and shall meet the following criteria:

(A) have Medicare certification and a Medicare end-stage renal disease (ESRD) provider number;

(B) be a current Texas Medicaid provider;

(C) be licensed by the Texas Department of Health (department) as an ESRD facility;

(D) reimburse KHC for any overpayments made to the facility by KHC upon request. KHC may withhold payment on claims submitted by the facility to recoup any overpayments; and

(E) not currently be on suspension as a KHC participating facility, as a Texas Medicaid provider, as a Medicare certified ESRD facility, or as a licensed Texas ESRD facility.

(2) KHC may contract with an outpatient dialysis facility located in another state if the out-of-state facility meets all the requirements of paragraph (1)(A), (B), and (D) of this subsection, and is licensed by their respective state, if applicable. Outpatient dialysis facilities located in another state may not currently be on suspension as a KHC participating facility, as a Medicaid provider in Texas or their respective state, as a Medicare certified ESRD facility, or by the ESRD licensing authority of their applicable state.

(3) Outpatient dialysis facilities or home health agencies with interim approval for Medicare participation will qualify for interim approval by KHC. Facility claims will not be paid by KHC until the facility receives final Medicare certification and a KHC contract is executed. Recipient applications for KHC eligibility may be submitted by the facility during the period of interim approval. Interim approval will last no longer than six months from the date of the initial KHC contact. If interim approval lapses before a KHC contract is executed, the interim approval will be terminated and claims submitted will not be paid.

(4) Pharmacies, including mail order pharmacies, shall enter into an agreement to participate in KHC through the Vendor Drug Program (VDP).

(5) Physicians providing services in the State of Texas shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:

(A) be licensed to practice medicine in the State of Texas;

(B) be a current Texas Medicaid provider;

(C) not currently be on suspension as a KHC participating provider, as a physician licensed to practice medicine in the State of Texas, or as a Texas Medicaid provider; and

(D) reimburse KHC for any overpayments made to the physician by KHC upon request. KHC may withhold payment on claims submitted by the physician to recoup any overpayments.

(6) Physicians providing services outside the State of Texas shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:

(A) be associated with a contracted out-of-state facility;

(B) be licensed to practice medicine in the state in which services are to be provided;

(C) be a current Texas Medicaid provider;

(D) not currently be on suspension as a KHC participating provider, as a physician licensed to practice medicine in the state in which services are to be provided, or as a Medicaid provider in Texas or their respective state; and

(E) reimburse KHC for any overpayments made to the physician by KHC upon request. KHC may withhold payment on claims submitted by the physician to recoup any overpayments.

(7) Hospitals shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:

(A) be licensed to provide hospital services in the State of Texas;

(B) be a current Texas Medicaid provider;

(C) have Medicare approval;

(D) not currently be on suspension as a KHC participating provider, as a hospital licensed to provide hospital services in the State of Texas, as a Texas Medicaid provider, or as a Medicare certified hospital; and

(E) reimburse KHC for any overpayments made to the hospital by KHC upon request. KHC may withhold payment on claims submitted by the hospital to recoup any overpayments.

(8) Out-of-state hospitals shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:

(A) be licensed to provide hospital services in the state in which services are to be provided;

(B) be a current Texas Medicaid provider;

(C) have Medicare certification;

(D) not currently be on suspension as a KHC participating provider, as a hospital licensed to provide hospital services in the state in which services are to be provided, as a Medicaid provider in Texas or their respective state, or as a Medicare certified hospital; and

(E) reimburse KHC for any overpayments made to the hospital by KHC upon request. KHC may withhold payment on claims submitted by the hospital to recoup any overpayments.

(b) Effective dates for participation in KHC are as follows:

(1) The effective date of all outpatient dialysis facility or home health care agency contracts shall be on or after the Medicare ESRD certification date.

(2) The effective date of all pharmacy agreements shall be determined by VDP.

(c) Reasons for suspension or termination from participation in KHC are as follows.

(1) Any participating facility, participating pharmacy, or provider may be terminated or suspended for:

(A) loss of approval or exclusion from participation in the Medicare program;

(B) exclusion from participation in the Medicaid program;

(C) providing false or misleading information regarding any participation criteria;

(D) a material breach of any contract or agreement with KHC;

(E) filing false or fraudulent claims with KHC; or

(F) failure to maintain the participation criteria contained in subsection (a) of this section.

(2) A participating facility, participating pharmacy, or provider may appeal a termination or suspension through the department's reconsideration and fair hearings process, as contained in §61.10 of this title (relating to Notice of Intent to Take Action and Reconsideration) and §61.11 of this title (relating to Notice and Fair Hearing).

(A) KHC may not terminate KHC participation until a final decision is rendered under the department's reconsideration and fair hearings process.

(B) KHC may withhold payments on claims pending final decision under the department's reconsideration and fair hearings process.

(C) KHC shall release any withheld payments and reinstate participation in KHC if the final determination is in favor of the participating facility, participating pharmacy, or provider.

(D) KHC shall not enter into, extend, or renew a contract or agreement with a participating facility, participating pharmacy, or provider until a final decision is rendered under the department's reconsideration and fair hearings process.

(E) A participating facility, participating pharmacy, or provider may not appeal a termination of a contract which results from limitations in appropriations or funding for covered services or benefits or which terminates under its own terms.

§61.10. Notice of Intent to Take Action and Reconsideration.

(a) When notice of intent to take action is required. A Kidney Health Care (KHC) applicant, recipient, or provider is entitled to a notice of intent to take action under this section anytime KHC intends to take action.

(b) Time of notice of intent to take action. A notice of intent to take action shall be mailed to the applicant, recipient, or provider not less than 20 days prior to the time KHC intends to take an action.

(c) Content of notice of intent to take action. The notice shall contain the following information:

(1) a statement of the action KHC intends to take;

(2) an explanation of the reasons for the action KHC intends to take;

(3) an explanation of the applicant's, recipient's, or provider's right to request a reconsideration before the action is taken;

(4) the procedure by which the applicant, recipient, or provider may request a reconsideration from KHC, including the address where written requests shall be submitted and any phone number the applicant, recipient, or provider may call to request assistance or a reconsideration; and

(5) a statement that the applicant, recipient, or provider shall make a request for reconsideration within 20 days of the date on the notice and that if the applicant, recipient, or provider does not request a reconsideration, the applicant's, recipient's, or provider's right to a reconsideration and fair hearing will be waived and the action will become final.

(d) No request. If a request for reconsideration is not received within the time allowed, the action shall become final 20 days after the date on the notice and the right to reconsideration or a fair hearing is waived.

(e) Reconsideration procedure. If an applicant, recipient, or provider contacts KHC requesting a reconsideration, KHC will conduct a review of the request and the action shall not become final until a decision is made as described in this subsection.

(1) KHC will conduct a comprehensive review of the request within 180 days of KHC's receipt of the request. KHC will:

(A) obtain any additional medical information or documentation required or available to support the request;

(B) review the request along with all supporting documentation; and

(C) send the notice required by paragraph (2) or (3) of this subsection.

(2) If KHC determines that the request is approved based on the comprehensive review, KHC will notify the applicant, recipient, or provider that the request is approved.

(3) If KHC determines that the request is not approved and that an action will be taken, KHC will notify the applicant, recipient, or provider of their right to a fair hearing as described in §61.11 of this title (relating to Notice and Fair Hearing).

§61.11. Notice and Fair Hearing.

(a) Notice required. An applicant, recipient, or provider will be notified of their right to a fair hearing if KHC does not approve the applicant's, recipient's, or provider's request after a reconsideration.

(b) Content of notice. The notice shall contain the following information:

(1) a statement of the action KHC intends to take;

(2) an explanation of the reasons for the action KHC intends to take;

(3) an explanation of the applicant's, recipient's, or provider's right to request a hearing;

(4) the procedure by which the applicant, recipient, or provider may request a fair hearing from the department, including the address where written requests shall be submitted;

(5) an explanation that the applicant, recipient, or provider may represent themselves, or use legal counsel, a relative, a friend, or another spokesperson;

(6) an explanation that the applicant, recipient, or provider may request that the fair hearing be conducted based on the written information used in the reconsideration process and any additional written information submitted without the necessity of taking oral testimony; and

(7) a statement that the applicant, recipient, or provider shall make a request for a fair hearing within 20 days of the date of the notice and that if the applicant, recipient, or provider does not request a fair hearing, the applicant's, recipient's, or provider's right to a fair hearing will be waived.

(c) Fair hearing procedure. A fair hearing will be conducted under the department's fair hearing procedures at §§1.51 - 1.55 of this title (relating to Fair Hearing Procedures).

(d) Fair hearing decisions. A final decision shall be made by the department within 90 days from the date the applicant, recipient, or provider makes a request for a fair hearing, unless waived in writing by the applicant, recipient, or provider.

§61.12. Kidney Health Care Advisory Committee.

(a) The committee. An advisory committee shall be appointed under and governed by this section.

(1) The name of the committee shall be the Kidney Health Care Advisory Committee (committee).

(2) The committee is established under the Health and Safety Code, §11.016 which allows the Board of Health (board) to establish advisory committees.

(b) Applicable law. The committee is subject to the Government Code, Chapter 2110, concerning state agency advisory committees.

(c) Purpose. The purpose of the committee is to provide advice to the board in the area of end-stage renal disease (ESRD) and to provide advice on current state-of-the-art treatment modalities, medication therapies, and prioritization of the needs of ESRD patients in Texas.

(d) Tasks.

(1) The committee shall advise the board concerning rules relating to the Kidney Health Care program (KHC).

(2) The committee shall:

(A) make recommendations regarding benefits to be provided by KHC;

(B) provide advice on the coordination of departmental and kidney health care activities with activities of other agencies and organizations involved in ESRD; and

(C) secure the cooperation and active participation of agencies and organizations that may contribute to the effectiveness of KHC.

(3) The committee shall carry out any other tasks given to the committee by the board.

(e) Committee abolished. By March 1, 2008, the board will initiate and complete a review of the committee to determine whether the committee should be continued, consolidated with another committee, or abolished. If the committee is not continued or consolidated, the committee shall be abolished on that date.

(f) Composition. The committee shall be composed of nine members appointed by the board. The composition of the committee shall include three consumer representatives and six nonconsumer representatives.

(1) The six nonconsumer representatives shall be as follows:

(A) three physicians who are nephrologists or renal transplant surgeons; and

(B) three persons who are renal social workers, renal nurses, renal dietitians, dialysis technicians, renal administrators or pharmacists.

(g) Terms of office. The term of office of each member shall be six years. Members shall serve after expiration of their term until a replacement is appointed.

(1) Members shall be appointed for staggered terms so that the terms of three members will expire on December 31st of each even-numbered year.

(2) If a vacancy occurs, a person shall be appointed to serve the unexpired portion of that term.

(h) Officers. The committee shall select from its members the presiding officer and an assistant presiding officer to begin serving on March 1 of each odd-numbered year.

(1) Each officer shall serve until February 27th of each odd-numbered year. Each officer may holdover until his or her replacement is elected.

(2) The presiding officer shall preside at all committee meetings at which he or she is in attendance, call meetings in accordance with this section, appoint subcommittees of the committee as necessary, and cause proper reports to be made to the board. The presiding officer may serve as an ex-officio member of any subcommittee of the committee.

(3) The assistant presiding officer shall perform the duties of the presiding officer in case of the absence or disability of the presiding officer. In case the office of presiding officer becomes vacant, the assistant presiding officer will complete the unexpired portion of the term of the office of presiding officer.

(4) If the office of assistant presiding officer becomes vacant, it may be filled by vote of the committee.

(5) A member shall serve no more than two consecutive terms as presiding officer and/or assistant presiding officer.

(6) The committee may reference its officers by other terms, such as chairperson and vice-chairperson.

(i) Meetings. The committee shall meet only as necessary to conduct committee business.

(1) A meeting may be called by agreement of department staff and either the presiding officer or at least three members of the committee.

(2) Meeting arrangements shall be made by department staff. Department staff shall contact committee members to determine availability for a meeting date and place.

(3) The committee is not a "governmental body" as defined in the Open Meetings Act. However, in order to promote public participation, each meeting of the committee shall be announced and conducted in accordance with the Open Meetings Act, Texas Government Code, Chapter 551, with the exception that the provisions allowing executive sessions shall not apply.

(4) Each member of the committee shall be informed of a committee meeting at least five working days before the meeting.

(5) A quorum for the purpose of transacting official business is five members.

(6) The committee is authorized to transact official business only when in a legally constituted meeting with a quorum present.

(7) The agenda for each committee meeting shall include an item entitled public comment under which any person will be allowed to address the committee on matters relating to committee business. The presiding officer may establish procedures for public comment, including a time limit on each comment.

(j) Attendance. Members shall attend committee meetings as scheduled. Members shall attend meetings of subcommittees to which the member is assigned.

(1) A member shall notify the presiding officer or appropriate department staff if he or she is unable to attend a scheduled meeting.

(2) It is grounds for removal from the committee if a member cannot discharge the member's duties for a substantial part of the term for which the member is appointed because of illness or disability, is absent from more than half of the committee and subcommittee meetings during a calendar year, or is absent from at least three consecutive committee meetings.

(3) The validity of an action of the committee is not affected by the fact that it is taken when a ground for removal of a member exists.

(k) Staff. Staff support for the committee shall be provided by the department.

(l) Procedures. Roberts Rules of Order, Newly Revised, shall be the basis of parliamentary decisions except where otherwise provided by law or rule.

(1) Any action taken by the committee must be approved by a majority vote of the members present once a quorum is established.

(2) Each member shall have one vote.

(3) A member may not authorize another individual to represent the member by proxy.

(4) The committee shall make decisions in the discharge of its duties without discrimination based on any person's race, creed, gender, religion, national origin, age, physical condition, or economic status.

(5) Minutes of each committee meeting shall be taken by department staff.

(A) A draft of the minutes approved by the presiding officer shall be provided to the board and each member of the committee within 30 days of each meeting.

(B) After approval by the committee, the minutes shall be signed by the presiding officer.

(m) Subcommittees. The committee may establish subcommittees as necessary to assist the committee in carrying out its duties.

(1) The presiding officer shall appoint members of the committee to serve on subcommittees and to act as subcommittee chairpersons. The presiding officer may also appoint nonmembers of the committee to serve on subcommittees.

(2) Subcommittees shall meet when called by the subcommittee chairperson or when so directed by the committee.

(3) A subcommittee chairperson shall make regular reports to the advisory committee at each committee meeting or in interim written reports as needed. The reports shall include an executive summary or minutes of each subcommittee meeting.

(n) Statement by members.

(1) The board, the department, and the committee shall not be bound in any way by any statement or action on the part of any committee member except when a statement or action is in pursuit of specific instructions from the board, department, or committee.

(2) The committee and its members may not participate in legislative activity in the name of the board, the department, or the committee except with approval through the department's legislative process. Committee members are not prohibited from representing themselves or other entities in the legislative process.

(3) A committee member should not accept or solicit any benefit that might reasonably tend to influence the member in the discharge of the member's official duties.

(4) A committee member should not disclose confidential information acquired through his or her committee membership.

(5) A committee member should not knowingly solicit, accept, or agree to accept any benefit for having exercised the member's official powers or duties in favor of another person.

(6) A committee member who has a personal or private interest in a matter pending before the committee shall publicly disclose the fact in a committee meeting and may not vote or otherwise participate in the matter. The phrase "personal or private interest" means the committee member has a direct pecuniary interest in the matter but does not include the committee member's engagement in a profession, trade, or occupation when the member's interest is the same as all others similarly engaged in the profession, trade, or occupation.

(o) Reports to board. The committee shall file an annual written report with the board.

(1) The report shall list the meeting dates of the committee and any subcommittees, the attendance records of its members, a brief description of actions taken by the committee, a description of how the committee has accomplished the tasks given to the committee by the board, the status of any rules which were recommended by the committee to the board, and anticipated activities of the committee for the next year.

(2) The report shall identify the costs related to the committee's existence, including the cost of agency staff time spent in support of the committee's activities and the source of funds used to support the committee's activities.

(3) The report shall cover the meetings and activities in the immediate preceding 12 months and shall be filed with the board each March. It shall be signed by the presiding officer and appropriate department staff.

(p) Reimbursement for expenses. In accordance with the requirements set forth in the Government Code, Chapter 2110, a committee member may receive reimbursement for the member's expenses incurred for each day the member engages in official committee business if authorized by the General Appropriations Act or budget execution process.

(1) No compensatory per diem shall be paid to committee members unless required by law.

(2) A committee member who is an employee of a state agency, other than the department, may not receive reimbursement for expenses from the department.

(3) A nonmember of the committee who is appointed to serve on a subcommittee may not receive reimbursement for expenses from the department.

(4) Each member who is to be reimbursed for expenses shall submit to department staff the member's receipts for expenses and any required official forms no later than 14 days after each committee meeting.

(5) Requests for reimbursement of expenses shall be made on official state travel vouchers prepared by department staff.

§61.13. Forms. Forms which have been developed by the Texas Department of Health (department) for use in the Bureau of Kidney Health Care (KHC) will be provided to applicants, participating facilities, and providers, as necessary.

§61.14. Confidentiality of Information.

(a) All information required by this chapter to be submitted may be verified at the discretion of the Texas Department of Health (department) and without notice to the applicant or recipient of benefits of the Kidney Health Care program (KHC), or to the providers of KHC services. This information is confidential to the extent authorized by law.

(b) Information may be disclosed in summary, statistical, or other forms which does not identify particular individuals.

§61.15. Nondiscrimination Statement. The Texas Department of Health (department) operates in compliance with the Civil Rights Act of 1964, Title VI (Public Law 88-352); 45 Code of Federal Regulations Part 80 so that no person will be excluded for participation in, be denied benefits, or otherwise subjected to discrimination on the grounds of race, color, or national origin, sex, creed, handicap or age.

STATUTORY AUTHORITY: The Texas Health and Safety Code, Chapter 42, provides the Texas Department of Health with the authority to adopt rules to provide adequate kidney care and treatment for the citizens of the State of Texas and to carry out the purposes and intent of the Texas Kidney Health Care Act; and §12.001, which provides the Board of Health with the authority to adopt rules for the performance of every duty imposed by law on the Board, the Department, and the Commissioner of Health.

EFFECTIVE DATES:
Original rules effective June 29, 1976;
Original rules repealed and new rules adopted effective September 1, 1982;
Amendments to §61.3, 61.8, & 61.9 effective January 7, 1983;
Amendments throughout effective September 16, 1983;
Amendments to §61.1 - 61.4 effective January 4, 1984;
Amendments to §61.4 & 61.6 effective June 5, 1984;
Amendments to §61.1 - 61.4, 61.6 & 61.8 - 61.9 effective September 4, 1984.
Amendments to §61.3 effective February 12, 1985.
Amendments to §61.1 - 61.10, 61.12 & 61.3 effective September 1, 1985.
Amendments to §61.2 - 61.4, 61.7 & 61.10 effective December 30, 1985.
Amendments to §61.1 & 61.3 - 61.10 effective September 8, 1986.
Amendments to §61.1 - 61.4 and 61.6 - 61.14 effective December 29, 1987.
Amendments to §61.1 - 61.4 and 61.6, 61.7, 61.9 effective November 28, 1988.
Amendments to §61.1, 61.3, 61.4, 61.6 - 61.9 and 61.11 effective January 2, 1990.
Amendments to §61.3 and 61.4 effective April 9, 1991.
§61.15 added and effective December 12, 1994.
Entire rules repealed and new rules adopted effective March 13, 1997.

Amendments to §61.12 effective February 4, 1999.
Amendments to §§61.1 – 61.9 effective August 15, 1999.
Amendments to §61.12 effective February 6, 2003

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